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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/981,824 | 09/18/1998 | JOSEF ENDL | P564-7029 | 8523 |

6449 7590 07/30/2003

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EXAMINER

EWOLDT, GERALD R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 07/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/981,824

Applicant(s)

Endl et al.

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/03/03 and 5/20/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-59 is/are pending in the application.
- 4a) Of the above, claim(s) 6-17 and 19-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 18, and 55-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

1. Claims 1-3, 5, and 18, and newly added Claims 55-59 are being acted upon.

2. Applicant's amendments and response, filed 2/03/03 and 5/20/03, are acknowledged. In view of the instant amendment and response, the previous rejections under the first and second paragraphs of 35 U.S.C. 112 have been withdrawn.

3. Applicant's proposed drawing changes, filed 5/20/03, would be acceptable if incorporated into the drawings.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled requirements of paragraphs (1), (2), and (4) of section 3c of this title before the invention thereof by the applicant for patent.

5. Claims 1-3, 5, 18, and newly added Claims 55-59 stand/are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07992 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01 and maintained in Paper No. 29, mailed 10/01/02.

Applicant's arguments, filed 2/03/03, have been fully considered but they are not persuasive. Applicant argues that the amending of "comprising" to "consisting essentially of" obviates the rejection.

It is the Examiner's position that the aforementioned change has not materially affected the scope of the claims:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that

the introduction of additional steps or components would materially change the characteristics of applicant's invention MPEP 2111.03.

Note that the claims are drawn to peptides comprising lengths of from 6 amino acids to 25 amino acids additionally comprising an essentially unlimited number of substitutions, mutations, or chemical derivatizations. Absent any showing in the specification, Applicant cannot now persuasively argue that the claims encompass a multitude of peptides, but excluding those applied as prior art. Regarding the seemingly narrower scope of Claims 57 and 59, while the first line of Claim 57 recites "consisting of", line 16 recites "comprises". This mixing of terms that seemingly limit and broaden the scope of the claims at the same time is considered in its broader sense for search purposes. Additionally, given the construction of the claim, the "consisting of" limitation reads only on the amino acid sequence of SEQ ID NO:7 and not the derivations of part (i).

6. Claims 1-3, 5, 18, and newly added Claims 55-59 stand/are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,011,139 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01 and maintained in Paper No. 29, mailed 10/01/02.

Applicant's arguments, filed 2/03/03, have been fully considered but they are not persuasive. Applicant argues that the newly added definition of "peptide derivative" obviates the rejection.

It is the Examiner's position that the peptide of the prior art is still considered a derivative of the claimed peptide in that it has been derivatized by the addition of 2 amino acids at the N-terminus and the removal of the C-terminus Ile. Said additions and removal would be encompassed as a "peptide derivatized by a chemical reaction" as the formation and breaking of peptide bonds are chemical reactions.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5, 18, and newly added Claims 55-59 stand/are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 95/07992 (of record) or U.S. Patent No. 6,011,139 (of record) each in view of U.S. Patent No. 5,750,114 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01 and maintained in Paper No. 29, mailed 10/01/02.

Applicant's arguments, filed 2/03/03, have been fully considered but they are not persuasive. Applicant argues that as the primary references are deficient given the instant amendments, as set forth in the previous arguments, the instant combination of references fails to teach or suggest the claimed invention.

See the Examiner's position as set forth in Sections 5 and 6 above.

9. The following are new grounds for rejection.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3, 5, 18, and newly added Claims 55-59 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

A) "peptide derivative ... in which at least one amino acid has been replaced" in Claim 1 and 57.

Applicant's amendment, filed 2/03/03 asserts that no new matter has been introduced into the claims. However, the specification cannot support "at least one amino acid" in the instant claim text. The specification discloses only "one or several amino acids".

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 57 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the recitation of "consisting of" in line 1 and "comprises" in line 16 of Claim 57 renders the claims vague and indefinite as it is unclear whether Applicant intends to limit the scope of the claims (consisting of) or broaden the scope of the claims (comprises). Accordingly, the metes and bounds of the claims are unclear.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
July 29, 2003